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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/759,644 | 01/16/2004 | Jeffrey I. Auerbach | INL-083CP6C5 | 8755 |

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| EXAMINER |
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HORLICK, KENNETH R

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| ART UNIT | PAPER NUMBER |
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1637

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/29/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/759,644

Applicant(s)

AUERBACH, JEFFREY I.

Examiner

Kenneth R. Horlick

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-26,30 and 65-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26,30 and 65-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>1/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

1. The claims are objected to because of the following informality: in new claims 65, 67, and 74, "kit" is misspelled as "kid". Correction is required.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended/new claims 23-26, 30, and 65-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter).

Independent claims 23 and 69 recite the language "at least one primer", the scope of which includes no upper limit. Despite the remarks in the papers filed 12/29/06, support for this language has not been found in the specification. Further, no support has been found for the language "a circular nucleic acid molecule" in independent claim 69; the scope of this language is unlimited whereas the specification appears to be limited to embodiments wherein the circular nucleic acid molecule comprises a recombinational site. If this rejection is traversed, it is requested that support be pointed to with particularity (page and line numbers).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Amended/new claims 23-26, 30, and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US 5,270,184) in view of Mullis et al. (US 4,683,195).

Independent claim 23 is drawn to a kit comprising: at least one primer; and a polymerase capable of isothermal amplification. It is noted that the language regarding "rolling circle amplification" and "a circular nucleic acid molecule such that the extension of the at least one primer forms a rolling circle replicon" relates solely to "intended use" of the kit, and thus cannot be given patentable weight. That is, this language does not limit the actual kit components, which are at least one primer and a polymerase.

Walker et al. disclose a method comprising the use of: a plurality of single-stranded polynucleotide primers; and a polymerase having strand displacement ability and able to exponentially amplify nucleic acids at a constant temperature (see entire document, especially Fig. 1 and columns 6-13). This patent also discloses the use of ligase and restriction enzymes (see column 13, lines 30-34), as well as nucleotide mixtures comprising nucleotide analogs (see Figs. 2 and 3).

Walker et al. do not disclose kits.

Mullis et al. disclose kits (see column 3, lines 34-55).

One of ordinary skill in the art would have been motivated to package together the primers and polymerase of Walker et al. into a kit because such a kit would have clearly been useful in carrying out the method of Walker et al. As demonstrated by Mullis et al., the use of kits for facilitating the practice of methods was conventional in the art at the time of the invention. The limitations of the dependent claims are merely drawn to conventional reagents used in nucleic acid manipulation and thus clearly do not contribute to patentability of the claimed kits. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

4. With respect to the above rejection, the arguments of the response filed 12/29/06 have been fully considered, but are not found persuasive. As explained above, the claims are drawn to kits comprising at least one primer and a polymerase capable of isothermal amplification, and not to methods of rolling circle amplification using such reagents. Thus, the arguments of the response regarding "intended use" of the kit and kit components do not relate to actual claim limitations which can be given patentable weight.

5. Claims 23-26, 30, and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lizardi (US 6,124,120).

Lizardi discloses a method comprising the use of: a plurality of single-stranded polynucleotide primers; and a polymerase having strand displacement ability and able

Art Unit: 1637

to exponentially amplify nucleic acids at a constant temperature (see entire document, especially columns 2-3, 6, 8-10, and 16). Lizardi also disclose in column 17, lines 24-26, the use of kits.

Lizardi does not explicitly disclose the exact kits of the claims.

One of ordinary skill in the art would have been motivated to package together the primers and polymerase of Lizardi et al. into a kit because such a kit would have clearly been useful in carrying out the method of Lizardi. Although Lizardi only discloses generic kits, surely the claimed kits would have been suggested since they comprise required reagents for the method of Lizardi. The limitations of the dependent claims are merely drawn to conventional reagents used in nucleic acid manipulation and thus clearly do not contribute to patentability of the claimed kits. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

6. With respect to the above rejection, the arguments of the response filed 12/29/06 have been fully considered, but are not found persuasive. The response argues that Lizardi '120 is not prior art because the instant claims are entitled to priority back to the filing date of the parent '945 application which is August 24, 1992. However, as noted above in paragraph 2, support for the amended claim language has not been found in the instant specification; for the same reasons support has not been found in the parent '945 application. Thus, Lizardi is still considered prior art, and the rejection is maintained.

7. New claims 69-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (US 5,149,777) in view of Mullis et al. (US 4,683,195).

Independent claim 69 is drawn to a kit comprising: a circular nucleic acid molecule; at least one primer able to bind thereto; and a polymerase capable of isothermal amplification. It is noted that the language regarding "rolling circle amplification" and "exponentially amplify said circular nucleic acid molecule under an isothermal condition" relates solely to "intended use" of the kit, and thus cannot be given patentable weight. That is, this language does not limit the actual kit components, which are a circular nucleic acid molecule, at least one primer capable of binding thereto, and a polymerase having potential isothermal amplification capability.

Hansen et al. disclose a method comprising the use of: a circular nucleic acid molecule (M13 vector); at least one primer able to bind thereto; and a polymerase which is inherently capable of isothermal amplification (Klenow) (see column 3, line 50 to column 6, line 42).

Hansen et al. do not disclose kits.

Mullis et al., as discussed above, discloses kits comprising primers and polymerase.

One of ordinary skill in the art would have been motivated to package together the circular nucleic acid, primer, and Klenow polymerase of Hansen et al. into a kit because such a kit would have clearly been useful in carrying out the method of Hansen et al. As demonstrated by Mullis et al., the use of kits for facilitating the practice of methods was conventional in the art at the time of the invention. The limitations of the

Art Unit: 1637

dependent claims are merely drawn to conventional reagents used in nucleic acid manipulation and thus clearly do not contribute to patentability of the claimed kits. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 23-26, 30, and 65-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,740,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus.

10. Claims 23-26, 30, and 65-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,448,017. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus.

11. Regarding the above two obviousness-type double patenting rejections, the response requests that this issue be held in abeyance.

12. No claims are free of the prior art.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

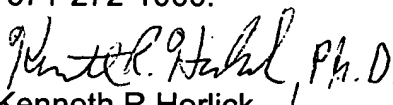
Art Unit: 1637

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

03/20/07